

Figure 2 and support for claim 16 may be found, e.g., in Figure 6. Claim 17 is amended only to correctly refer to SEQ ID NO:3 instead of Sequence I.D. No. 3. None of these amendments adds new matter to the specification. Entry of these amendments is respectfully requested.

In point 4 of the Office Action, the Examiner requests that the Applicants provide a substitute specification. A clean, unmarked substitute specification is provided with this amendment. According to 37 CFR, section 1.125, a marked-up copy of the substitute specification showing the matter being added to and the matter being deleted from the specification of record is also provided. No new matter is added in this substitute specification. OK

In point 5 of the Office Action, the Examiner rejects claims 14 and 18-20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 4,876,194. The Examiner maintains that the L protein disclosed in the '194 patent has the ability to bind immunoglobulin light chains and contains fragments with the same property, or an obvious variant of the present invention comprising SEQ ID NO:1 or specified domains of L protein.

Applicants submit that the current claims recite that the protein is selected from the group consisting of a protein comprising SEQ ID NO:1, or a specific domain thereof, now further defined in the instant claims by amino acid positions and which are defined in the specification. The '194 patent fails to identify any sequence of an L protein or define the domains for any fragment thereof that binds to immunoglobulin light chains. Moreover, as set forth in the attached Declaration of Dr. Ulf Sjöbring, obtaining the sequence of the L protein and identification of particular domains that bind immunoglobulin light chains was unusually difficult. Accordingly, one of ordinary skill in the art could not easily expect to obtain the present sequences and domains thereof based on the 95 kD gel identified protein. Furthermore, possession of a protein and/or a description of a property of that protein, e.g., a 95kD band on a gel, does not render the sequence of the protein or definition of the functional domains obvious.

Obviousness-type double patenting pertains to claims drawn to obvious variations of a previously patented invention. In light of the attached Declaration of Dr. Sjöbring regarding the difficulty of obtaining the sequence of SEQ ID NO:1 and the above remarks, Applicants submit that the instantly claimed SEQ ID NO:1 and the binding domains thereof are non-obvious over the teaching of the '194 patent and respectfully request withdrawal of the rejection.

In point 5 of the Office Action, claims 15-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 4,876,194 in view of Guss et al. (WO 87/05361) (please note that this reference should be cited as WO 87/05631) and Kastern et al. The Examiner believes that it would be obvious to one of ordinary skill in the art at the time the invention was made to link protein L, as taught by U.S. Patent No. 4,876,194, with protein G or the C1, C2, or C3 domains thereof taught by Guss et al.

The Applicants respectfully traverse these grounds of rejection. In *Winner International Royalty Corp. v. Wang*, No. 96-2107, 48 USPQ.2d 1139 (D.C.D.C 1998), the court held:

...invention cannot be found obvious unless there was some **explicit** teaching or suggestion in art to motivate one of ordinary skill to combine elements so as to create same invention.

(Emphasis added.) Guss et al. teaches Protein G. However, Guss et al. does not teach protein L nor does Guss et al. explicitly teach the combination of any domain of protein G with protein L. Furthermore, as outlined in the Declaration of Dr. Sjöbring submitted herewith pursuant to 37 C.F.R. 1.132, obtaining the sequence of the L protein and identification of particular domains that bind immunoglobulin light chain was unusually difficult. Therefore, one of ordinary skill in the art could not easily expect to obtain the present sequence and domains thereof based on the 95 kD protein taught in U.S. Patent No. 4,876,194. Moreover, there is thus neither the means nor the motivation to combine. Reconsideration and withdrawal of the rejection are respectfully requested in view of the above remarks.

In point 6 of the Office Action, the Examiner rejects claims 14 and 18-20 under 35 U.S.C. 102(a) as being anticipated by Kastern et al. 1992 (*J. Biol Chem.* 267(18):12820-25). In this regard, the Applicants submit herewith a Declaration pursuant to 37 C.F.R. 1.132, stating that Kastern et al. is the work of the named inventors. The Applicants respectfully submit that the rejection of the claims has been obviated and requests that the Examiner withdraw this ground of rejection.

In point 7 of the Office Action, the Examiner rejects claims 14 and 18-20 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,876,194. As outlined in the

Declaration submitted herewith pursuant to 37 C.F.R. 1.132, obtaining the sequence of the L protein and identification of particular domains that bind immunoglobulin light chain was unusually difficult. Therefore, it would not have been obvious to one of ordinary skill in the art as to how to obtain the present sequence and domains thereof based on the 95 kD protein taught in U.S. Patent No. 4,876,194. In view of the Declaration of Dr. Sjöbring submitted herewith, reconsideration and withdrawal of the rejection are respectfully requested.

In point 9 of the Office Action, the Examiner rejects claim 20 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner alleges that the specification has not enabled (how to use) a pharmaceutical composition in that the specification does not describe what disease or infection the pharmaceutical composition is to be used to treat.

Without acquiescing to the rejections of the Examiner, Applicants have canceled claim 20. Applicants submit that this ground for rejection has thus been obviated and respectfully request its withdrawal. Applicants reserve the right to prosecute the subject matter of pharmaceutical compositions comprising the compositions of the instant application in a related or continuation application.

In point 10 of the Office Action, the Examiner points out several references that should be updated and also encourages the Applicants to review the entire application. The references have been updated in the substitute specification submitted herewith. Minor typographical errors have also been corrected.

In point 11 of the Office Action, the Examiner rejects claims 14-20 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter. The Examiner alleges that the claims are vague and indefinite in the recitation of the various domains and the SEQ ID NO:1 and 3. The Examiner requested that the Applicants define the amino acid sequence positions in the SEQ ID NO that set forth the domains. Without acquiescing in the assertion of the Office Action, the Applicants have amended claims 14 and 16 accordingly. Support for the amended claim 14 can be found, for example, in Figure 2, and support for the amended claim 16 can be found, for example in Figure

6. In view of the amended claims, reconsideration and withdrawal of the rejection are respectfully requested.

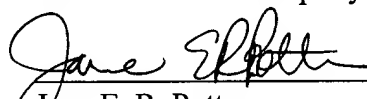
Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE.**"

In view of the above claim amendments and remarks, Applicants submit that the claims are now in condition for allowance and request that the Examiner issue a Notice to that effect.



Respectfully submitted,

Seed Intellectual Property Law Group PLLC



Jane E. R. Potter
Registration No. 33,332

Enclosures:

(JEP:cew) #44082

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the specification:

Please see enclosed substitute specification.

In the claims:

14. (Twice Amended) A protein having the ability to bind to the light chains of immunoglobulins, selected from the group consisting of:
- (a) a protein comprising the amino acid sequence of SEQ ID NO: 1;
 - (b) a protein comprising the amino acid sequence of at least one of the domains B1, B2, B3 or B4 of (a)[; and] wherein,
 - (i) domain B1 is comprised of from amino acid 5 to amino acid 80 of SEQ ID NO:1;
 - (ii) domain B2 is comprised of from amino acid 81 to amino acid 152 of SEQ ID NO:1
 - (iii) domain B3 is comprised of from amino acid 153 to amino acid 224 of SEQ ID NO:1
 - (iv) domain B4 is comprised of from amino acid 225 to amino acid 296 of SEQ ID NO:1; and
 - (c) a protein comprising the sequence of multiples or mixtures of the domains of B1, B2, B3 or B4 of [(a)](b).
16. (Amended) A hybrid protein according to claim 15, wherein the domains which bind to heavy chains of immunoglobulin G are chosen from among [the C1- and C2- domains in protein G; the A-, B- and C- domains in protein H; the A-, B1-, B2- and S domains in protein M1 or the E-, D-, A-, B- and C- domains in protein A] :
- (i) the C1- and C2- domains in protein G, wherein domain C1 is comprised of from amino acid 303 to amino acid 357 of protein G

and domain C2 is comprised of from amino acid 373 to amino acid 427 of protein G;

- (ii) the A-, B- and C1- domains in protein H wherein domain A is comprised of from amino acid 42 to amino acid 121 of protein H, domain B is comprised of from amino acid 122 to amino acid 158 of protein H, and domain C1 is comprised of from amino acid 159 to amino acid 200 of protein H;
- (iii) the A-, B1-, B2- and S domains in protein M1, wherein domain A is comprised of from amino acid 1 to amino acid 91 of protein M1, domain B1- is comprised of from amino acid 92 to amino acid 119 of protein M1, domain B2- is comprised of from amino acid 120 to amino acid 147 of protein M1, and domain S is comprised of from amino acid 154 to amino acid 190 of protein M1; or
- (iv) the E-, D-, A-, B- and C- domains in protein A, wherein domain E- is comprised of from amino acid 37 to amino acid 92 of protein A, domain D- is comprised of from amino acid 93 to amino acid 153 of protein A, domain A- is comprised of from amino acid 154 to amino acid 211 of protein A, domain B- is comprised of from amino acid 212 to amino acid 269 of protein A, and domain C- is comprised of from amino acid 270 to amino acid 327 of protein A.

17. (Amended) A hybrid protein according to claim 16, wherein the hybrid protein has the amino acid sequence of [Sequence I.D. No. 3] SEQ ID NO:3.